Protocol Authoring Tasks

	Cancer Center	Coop. Group	NCI
PI Tasks	•Review new agent info •Develop protocol ideas •Formulate study hypotheses •Develop study schema •Develop drug safety measures •Define study data to be collected •Prepare informed consent documents	•Review new agent info •Develop protocol ideas •Formulate study hypotheses •Develop study schema •Develop drug safety measures •Define study data to be collected •Prepare informed consent documents	•Author protocol instructions •Provide access to protocol submission guidelines
		•Approve protocol ideas	•Provide informal feedback on protocols
	•Conduct internal peer review of protocol ideas •Assist PI in developing Protocols •Review/approve protocols •Submit protocol to NCI •Determine drug supply and distribution	•Review draft protocol documents •Assist PI in developing Protocols •Review/approve Protocols •Submit protocol to NCI •Determine drug supply and distribution	•Determine drug supply and distribution •Estab. regulatory requirements
	•Regulatory filings	•Regulatory filings	

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Protocol Management Tasks

	Cancer Center	Coop. Group	NCI
	•Abstract protocol info into protocol mgmt. systems •Create study database •Register investigators •Distribute completed protocol documents to registered investigators •Train staff assigned to trial RE: data collection requirements	•Abstract protocol info into protocol mgmt. systems •Create study database •Register investigators •Distribute completed protocol documents to registered investigators	•Abstract protocol info into protocol mgmt. systems •Review protocol document •Register investigators •Provide feedback and questions to PI and/or cooperative group
PI Tasks	•Answer NCI questions and modify protocol •Resubmit modified protocol	•Answer NCI questions and modify protocol •Resubmit modified protocol	
	•Review/approve modified Protocol •Update protocol info into protocol mgmt. systems •Set up audit procedures	•Review/approve modified Protocol •Update protocol info into protocol mgmt. systems •Set up audit procedures	•Monitor PI/group responses •Update protocol info into protocol mgmt. systems •Review and approve/reject Protocol •Assign study monitor •Set up audit procedures

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Protocol Execution Tasks

	Cancer Center	Coop. Group	NCI
	•Collect patient history/lab/ radiology information •Assess patient eligibility •Enroll patients •Treat patients •Record patient visit findings •Review patient data •Record patient data in study database	•Assess patient eligibility •Enroll patients •Review patient data •Record patient data in study database	•Review patient data •Record patient data in study database •Track study milestones •Monitor study accruals
PI Tasks	•Submit patient data to NCI and/or cooperative group •Report summary protocol info to NCI and/or cooperative group •Support clinical trial audits	•Submit patient data to NCI •Report summary protocol info to NCI •Support clinical trial audits	
	•Audit clinical trial practices •Report adverse events •Submit protocol amendments •Prepare documents needed to close the study	•Audit clinical trial practices •Report adverse events •Submit protocol amendments •Review protocol amendments •Review summary protocol info	•Audit clinical trial practices •Report adverse events •Review/approve protocol amendments •Review summary protocol info •Approve study termination

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Protocol Analysis Tasks

	Cancer Center	Coop. Group	NCI
	•Review case report forms (CRFs) for completeness and correctness •Correct erroneous CRFs	•Review case report forms (CRFs) for completeness and correctness •Require corrections to erroneous CRFs	
	•Enter CRF data into statistical System •Run validation tests on CRF data •Request clarification to resolve data anomalies •Export clean, valid CRF data to study database •Close study to enrollment •Analyze efficacy and safety data	•Enter CRF data into statistical System •Run validation tests on CRF data •Request clarification to resolve data anomalies •Export clean, valid CRF data to study database •Close study to enrollment •Analyze efficacy and safety data	
PI Tasks	•Request study amendment based on data analysis •Prepare interim and final reports •Present study findings •Publish study findings	•Request study amendment based on data analysis •Prepare interim and final reports •Present study findings •Publish study findings	•Review/approve study amendments •Receive study reports •Analyze study results •Disseminate study results throughout NCI •Identify opportunities for further research Audit study data
	•Support audit of study data		

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